RX For The Defense

The newsletter of the
Drug and Medical Device Committee

10/20/2020

Volume 28, Issue 3

Committee Leadership

In This Issue

Leadership Notes

Chair's Corner

By Gail Rodgers

Hello DMD Friends and Colleagues,

I write this from New York City on Day 972 of some iteration of lockdown. Maybe I am bad at math but it feels that long. I hope all of you and yours are safe, well, and have retained some shred of sanity. I was recently on a call and realized that I am close to ending my first year as Chair of this Committee and have not seen a single one of you in person during that year. Ah well, someday.

While Zoom or other virtual platforms are not the same as being in person, I have gotten over my video/Zoom aversion and have quite enjoyed connecting with family, friends, and colleagues virtually the past few months. Admit it, all of you get sick of zoom but still enjoy snooping into people's houses and seeing what their WFH looks like.

With that, I am looking forward to virtually connecting with you at the Virtual Annual Meeting October 21–23. If you are not already on board, it is quite economical at $99 for members and $199 for nonmembers.

And I am really looking forward to seeing my DMD family at our Virtual Seminar on November 5–6. It is also economically priced at $99 for members and $199 for non-members. We know that no one wants to Zoom all day, so this Seminar is much shorter. We took some of our favorite topics from the May program that was 2020'd and added a couple of new and exciting topics.

Our industry is one of the most uniquely suited to respond to COVID-19. You will hear directly from in-house counsel how their companies responded in unprecedented ways and collaborations to help in the fight against COVID-19 in America and countries around the globe.

You will hear a sought-after speaker present on Diversity of Perspective, something top of mind this year. We also have a presentation on how data analytics are transforming legal departments and firms as we head into the "new normal."

We will have our in-house breakout session, Young Lawyer Blockbuster, Community Service Projects, DRI for Life Workout, our Committee meeting and so much more.

Based on the post-Seminar surveys every year, we know that networking is critical to our Committee. We have scheduled ample time for coffee breaks and small group chats as well as evening cocktail hours and themed networking events. We even have a wine tasting!

Now is the time to network. If you have not already, please register at this link. https://dridrugmedicaldevice.pathable.co/agenda And invite a non-member or someone who has not previously attended our Seminar. Now is the time to support each other, network and continue to grow stronger as a Committee and, more importantly, as a Community.

I look forward to "seeing" everyone soon!

Stay well and sane.

Gail

Gail Rodgers *is a partner in the New York City office of DLA Piper. She concentrates her practice in pharmaceutical and medical device litigation, mass torts and government and internal investigations. Gail represents clients on a wide variety of compliance matters, including the Foreign Corrupt Practices Act (FCPA) as well as advising and enhancing compliance programs in response to investigations. Gail has extensive experience in a wide variety of state and federal litigation, including providing strategic advice at each stage of litigation, managing national discovery teams, and implementation of national resolution programs. Gail serves as the Chair of the DRI Drug and Medical Device Committee.*

From the Editors

By Heather Howard and Jennifer A. Eppensteiner


Fall brings change. Our cold-brew coffees are now of the hot, pumpkin spice variety. We may soon trade flip-flops for scarves. More importantly, though, we are in a presidential election year with a vacancy on the Supreme Court. With that, we have one message for our readers: vote. Vote early, vote by mail, vote in-person, but regardless of how you do it, please vote.

After the election, we look forward to "seeing" you all at this year's virtual Drug and Medical Device Seminar, on November 5–6, 2020. We hope to reunite in-person in the new year.

Should you find yourself with extra time on your hands, or have an interesting topic idea for a future issue of *Rx for the Defense*, please contact Heather Howard at hhoward@kslaw.com or Jenn Eppensteiner at jeppensteiner@reedsmith.com to find out more information about the publication guidelines and the selection process.

Heather Howard *is Counsel in the Atlanta office of King & Spalding LLP, where she is a member of the firm's Trial & Global Disputes practice. She focuses her practice on the defense of pharmaceutical and medical device manufacturers in product liability suits at the trial level and on appeal. She serves as the Newsletter Editor for the DRI Drug and Medical Device Committee.*

Jennifer Eppensteiner *is a senior associate in Reed Smith LLP's Life Sciences Health Industry Group, resident in the Princeton, New Jersey office. Jennifer advises drug and medical device manufacturers on complex product liability litigation, including federal multidistrict litigation (MDL) and consolidated state court actions. Jennifer currently serves as the Assistant Newsletter Editor for the DRI Drug and Medical Device Committee as well as Young Lawyer liaison to the Drug and Medical Device Steering Committee.*

Legal Developments

Buckman Implied Preemption Wipes Out Misbranding Claims that a Product Is Not a Cosmetic *but a Drug*

By Kelly Jones Howell and Marina Plotkin

"Mirror, mirror on the wall, is this product I am using a cosmetic or is it a drug after all?"


Courts presiding over lawsuits where a plaintiff asserts misbranding or mislabeling claims that a defendant's product is not a cosmetic but a drug have provided a firm answer: the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §301 *et seq.*, (the "FDCA") impliedly preempts these claims. Since the FDA has exclusive enforcement power over the FDCA, a plaintiff cannot privately enforce alleged violations of the FDCA. 21 U.S.C. §337(a).

Intended use carves out the distinction between a cosmetic and drug under the FDCA. The terms cosmetic and drug are statutorily mutually exclusive—that is, a cosmetic is not a drug and a drug is not a cosmetic. Cosmetics are "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body…for cleansing, beautifying, promoting attractiveness, or altering the appearance." FCDA §201(i), (21 U.S.C. §321(i)). Drugs are defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles […] intended to affect the structure or any function of the body […]." 21 U.S.C. §321(g)(1). Over-the-counter (OTC) drugs are drugs that can be purchased without a doctor's prescription or consultation from a pharmacist. When a product meets the criteria as a cosmetic and an OTC drug, its labeling must

comply with the regulations for both cosmetic ingredient and OTC drug labeling. 21 CFR §701.3(d).

Most drugs—but not cosmetics—require pre-market approval. As such, the legal and regulatory framework of drugs significantly differ from cosmetics. A cosmetic is misbranded under the FDCA when marketed with drug claims without undergoing the pre-market approval process. Determining the distinction between a cosmetic and drug is a question reserved exclusively by the FDA, which has exclusive enforcement of FDCA violations. 21 U.S.C. §337(a).

Increasingly plaintiffs have filed class suits which creatively allege false advertisement claims for cosmetics labeled or marketed as a *drug*. Latching on to state-law analogs that either explicitly adopt the FDCA or incorporate its terms, these claims are predicated on the theory that by violating the FDCA, defendants in turn violate state law. The suits may also allege that the sale of the misbranded cosmetic constitutes a sale of an unapproved drug in violation of the FDCA and/or state law.

However, recent cases provide a framework for defending against these artful claims on implied preemption grounds. Courts seem to be sending the message to plaintiffs that the "narrow gap " revealed in *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2001) and its progeny is tightening.

A 2015 decision by the Eastern District of New York in *Elkind v. Revlon*, No. 14-CV-2482, 2015 WL 2344134 (E.D.N.Y. May 14, 2015), preempting mislabeling claims where plaintiffs alleged that the alleged mislabeling rendered defendant's Powder and Concealer products drugs not cosmetics, emphasized that plaintiffs' mislabeling claims do not exist independent of the FDCA. In this putative class action, plaintiffs claimed, among numerous other state law claims, that defendant's use of the phrases *"Age Defying [with] DNA Advantage*" and *"[H]elps protect skin's DNA to fight the signs of aging*" on its products manifested an intent that the products be used to manipulate the cells, rendering these products drugs as defined by FDCA. Plaintiffs argued that these products were mislabeled under the FDCA for not listing all of a drug's ingredients, and therefore violated New York and California laws prohibiting the unlawful sale of products. The court firmly rejected plaintiffs' mislabeling claims, as violations of the FDCA "lies squarely within the province of the FDA, and therefore "do not squeak through the narrow gap to escape express or implied preemption." *Id.* at *9.

Applying the reasoning in *Elkind,* in January 2016, the Northern District of New York in *Reid v. GMC Skin Care USA, Inc*., No. 8:15-CV-277, 2016 WL 403497, at *14 (N.D.N.Y. Jan. 15, 2016), dismissed plaintiffs' misbranding and mislabeling claims that defendant's stem cell skin care products violated the FDCA on preemption grounds. The court rejected plaintiffs' assertion that their claims were actionable under California and Washington law, not the FDCA. Plaintiffs' Complaint also alleged that defendant's stem cell products were misbranded because their labels violated FDCA regulations for over-the-counter drugs; that the products constituted unapproved drugs; and that "placing an unapproved drug into the stream of commerce is an independent wrongful act under the FDCA." *Id.* * 10. The court held that plaintiffs' claims disputing whether defendant's products were cosmetics or drugs were preempted under the FDCA. *Id.*

The April 2020 decision by a California District Court in *Somers v. Beiersdorf, Inc.,* 14cv2241-LAB (AGS), 2020 WL 1890575 (S.D. Cal. Apr. 15, 2020), granting defendant's motion for summary judgment on preemption grounds, reinforced that plaintiffs cannot privately enforce the FDCA. *Appeal docketed*, No. 20-55541 (9th Cir. May 19, 2020). In this proposed class action, plaintiffs alleged that defendant's sale of Nivea lotion was a "drug" and thus "unlawful" under California's Unfair Competition Law because it was sold without undergoing prior approval of the FDA. *Id.* at *1. Specifically, plaintiff alleged that the Nivea lotion label stating "*provides skin firming hydration," "improves skin's firmness [...],"* and *"proven to firm and tighten skin's surface [...]"* rendered it a drug under FDCA because it suggests the lotion is intended to "affect the structure of the body." *Id.* Having found plaintiffs' claims preempted under the FDCA, the court did not—and in fact *could not*—reach the question of whether the lotion at issue was a drug or a cosmetic. *Id.*

Echoing the *Buckman* proposition that a plaintiff's claims must "thread a narrow gap" to escape preemption, the court found—"[t]he plaintiff must be suing for conduct that *violates* the FDCA (or else [the] claim is expressly preempted by §360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Id.* at *3. Plaintiff's claim that the sale of the Nivea lotion without new drug approval under the federal act clearly indicates that Plaintiff was attempting to privately enforce the FDCA. Plaintiff's claim therefore could not avoid the broad sweep of the *Buckman* broom.

In a similar recent case, *Borchenko v. L'Oreal, Inc.,* 389 F. Supp. 3d 769 (C.D. Cal. 2019), a California federal court granted defendant's motion to dismiss for failure to state a claim on implied preemption grounds. Plaintiff commenced suit under the California Unfair Competition Law ("UCL") alleging that several of defendants' skin care products contained "skin structural representations" that rendered the products *drugs* under California's Sherman Food, Drug, and Cosmetic Law and the FDCA. *Id.* Plaintiff sought injunctive relief to prevent sale of the skin altering care products until defendant underwent the FDA New Drug Approval process ("NDA"). *Id*. at 773.

The court held that, first, plaintiff's UCL claim was a private enforcement of the FDCA and therefore interfered with the FDA's exclusive enforcement and regulatory authority. *Id.* Next, plaintiff's claims under the Sherman Law, which relies on and mirrors the parallel provisions of the FDCA, fail because "[the] Court cannot grant any relief to plaintiff without referring to and applying the provisions of the FDCA." Since plaintiff was suing *because* defendant's conduct violates the FDCA, plaintiff's claim was impliedly preempted.

The tidal force of the preemption waves revisited the East Coast. In its May 2020 decision, *Critcher v. L'Oreal USA, Inc.*, 959 F.3d 31 (2d Cir. 2020), the Second Circuit affirmed dismissal of state consumer protection claims and common law claims for unjust enrichment and breach of implied warranty of merchantability as preempted by the FDCA. Unable to squeeze liquid eye products down to the last drop, plaintiffs, former consumers, alleged that defendant deceived them into buying more cosmetics than they could use in violation of 21 U.S.C. §362(a). Plaintiffs argued that the state laws mirror the FDCA requirements that labels not be "false and misleading." *Id.* at 37.

Plaintiffs alleged that the liquid eye cream was misbranded because the label failed to accurately state the total amount of product, and that defendant failed to disclose that consumers will not be able to access the amount identified on the label. *Id.* at 36.

The court noted that federal law does not impose an obligation to disclose the usable net weight of a cosmetic. The court concluded, "Plaintiffs cannot avoid the sweeping preemptive force of the FDCA. Their state law claims—all of which seek to impose labeling requirements that are additional to, or different from, those that federal law has established—are barred." *Id.*

This line of cases illustrates that while plaintiffs' claims were well-greased, they could not slip through the narrow preemption gap. Defendants may use these cases as analogies to prevail on a motion to dismiss or summary judgment on implied preemption grounds.

Kelly Jones Howell *is a partner in the New York and New Jersey offices of Harris Beach. Her practice is focused on FDA-regulated product liability defense, including mass torts and class actions involving cosmetics and pharmaceuticals.*

Marina Plotkin *is a pharmacist lawyer at Harris Beach who utilizes her dual credentials to provide strategic insight on complex issues in the defense of product liability litigation, as well as the defense of pharmacies and pharmacists. The authors thank Christine D. Vasconcellos, a Law Clerk at Harris Beach, for her assistance with this article.*

Leading the Flock: Bellwether Selection in Complex Litigation

By Shana E. Russo, Jennifer A. Eppensteiner, and Kathy I. Oviedo

bell·weth·er: *noun,* **the leading sheep of a flock, with a bell on its neck.**



At seemingly every juncture, the all-important question is "who goes first." This is a constant whether you are reading the rules of a new board game or determining which case (or cases) will serve as your bellwether trial in a multidistrict litigation ("MDL"). As MDLs typically have hundreds, if not thousands, of pending cases, putting the right methods in place for bellwether selection early on will be essential to guide not only the trial selection process but also case-specific discovery.

One purpose of bellwether trials is to "produce a sufficient number of representative verdicts… to enable the parties and the court to determine the nature and strength of the claims, whether they can be fairly developed and litigated on a group basis, and what range of values the cases may have if resolution is attempted on a group basis." Manual for Complex Litigation (Fourth) §22.315 (2004). Identifying a representative discovery pool will likewise help the court and the parties to evaluate the claims and defenses related to common issues in the proceeding, such as *Daubert* issues and the admissibility of key evidence, and to understand the costs and burdens of subsequent litigation.

While there are various methods for selecting bellwether cases, the most critical element of any bellwether plan is that an honest representative sampling of cases be achieved. As articulated in the Bellwether Trial Selection Plan for the *Yasmin/Yaz* litigation, "[l]ittle credibility will be attached to this process, and it will be a waste of everyone's time and resources, if cases are selected which do not accurately reflect the run-of-the-mill case." *See* Amended Case Management Order No. 24 at II.3, Bellwether Trial Selection Plan, *In re: Yasmin and Yaz (Drospirenone) Mktg, Sales Practices and Prods. Liab. Litig.*, MDL No. 2100, 3:09-md-02100-DRH-PMF (S.D. Ill. Oct. 13, 2010).

This article will identify the possible methods of bellwether case selection, provide examples from recent MDLs, and discuss how the court in the Atrium C-Qur Mesh litigation directed the parties to pick the first bellwether trial.

Identifying Representative Plaintiffs

If "bellwether trials or test cases are to produce reliable information about other mass tort cases, the specific plaintiffs and their claims should be representative of the range of cases." *In re Hydroxycut Mktg. & Sales Practice Litig.*, No. 3:09-MD-2087-BTM KSC, 2012 WL 2522859, at *2 (S.D. Cal. June 29, 2012) (*citing* Manual for Complex Litigation (Fourth) §22.315 (2004)). "[T]o achieve its value ascertainment function for settlement purposes or to answer troubling causation or liability issues common to the universe of claimants," representativeness is a "core element" that must be present for a bellwether trial. *In re Chevron U.S.A. Inc.*, 109 F.3d 1016, 1019 (5th Cir. 1997).

The question, then, is how to identify the representative plaintiff for trial. U.S. District Court Judge Eldon E. Fallon, who has been responsible for overseeing the *Chinese Drywall* and *Xarelto* MDLs in the Eastern District of Louisiana, among others, explains "each transferee court that chooses to conduct its own bellwether trials must consider all the unique factual and legal aspects specific to its litigation and then fashion an appropriate, custom-made trial-selection formula." Hon. Eldon E. Fallon, et. al., *Bellwether Trials in Multidistrict Litigation*, 82 Tul. L. Rev. 2323, 2343 (June 2008). Three general steps, however, can be used to streamline the trial-selection process and help any MDL maximize its potential: (1) conducting a census of the existing litigation and dividing the cases into several distinct, easily ascertainable categories of cases; (2) selecting a manageable pool of cases, which reflects the various categories; and (3) selecting a predetermined number of individual cases within the sample and setting those cases for trial. *Id.*

Some factors to consider when conducting your census include "plaintiff characteristics; injuries; type(s) of claims brought; date when claims arose or case was filed (*e.g.,* before or after regulatory action, label change, or other major event); applicable law; circumstances of exposure (*e.g.,* length of exposure, dose, particular product at

issue, particular indication for use); type of defendant; defendant's market share; and availability of affirmative defenses." Melissa J. Whitney, *Bellwether Trials in MDL Proceedings, A Guide for Transferee Judges* (2019) at 22.

After determining the composition of the MDL and the size of the desired pool of bellwether plaintiffs, Judge Fallon suggests three selection methods: (1) random selection; (2) judicial selection; or (3) party selection.

Random Selection

When using random selection, individual cases can be selected either from the entire universe of the MDL or from within smaller subsets identified to represent certain variables. Judge Fallon cautions that random selection "can be problematic" because "there is no guarantee that the cases selected to fill the trial-selection pool will adequately represent the major variables"; however, empirical data has now been used to confirm "a random selection process can produce a sample of cases that are more like many other cases in the docket." Loren H. Brown, et. al., *Bellwether Trial Selection in Multi-District Litigation: Empirical Evidence in Favor of Random Selection*, Akron L. Rev.: Vol. 47: Iss. 3, Article 2, at 665 (2014). Random selection is endorsed by the Manual for Complex Litigation: "[t]o obtain the most representative cases from the available pool, a judge should direct the parties to select test cases randomly or limit the selection to cases that the parties agree are typical of the mix of cases." Manual for Complex Litigation (Fourth) §22.315 (2004).

The court in the *Abilify* MDL used random selection to fill its bellwether pool. With the help of a third-party litigation management services firm, the court selected one-hundred cases from the pool of completed Plaintiff Profile Forms to form its second discovery pool. *See* Order Regarding Selection of the Second Group of Potential Trial Cases, *In re: Abilify (Aripiprazole) Prod. Liab. Litig.*, Case No. 3:16-md-02734 (N.D. Fla. June 22, 2018) (Dkt. at 906). The court and the litigation management services firm then narrowed down the pool by "identify[ing] all Plaintiffs who checked the box for (a) either Bipolar Disorder or Major Depressive Disorder/Depression as the diagnosis leading to their Abilify prescription. . . the Plaintiff Profile Form, and (b) 'Gambling' as an obsessive/compulsive/impulsive behavior they claim was caused by Abilify. . ." *Id.* From that pool, the court randomly selected forty (40) cases to proceed to pretrial discovery. *Id.* Each side was then directed to notify the court of five cases to be removed from the pool, reducing the pool to thirty (30) cases. *Id.* at p. 2. Those thirty (30) cases then proceeded to case-specific discovery limited to medical, financial, and gambling records. *Id.* Each side was then directed to strike an additional five (5) cases, reducing the pool to twenty (20) cases, which proceeded to fact discovery. *Id.* at p. 3. The pool was then further reduced by each side selecting an additional five (5) to be struck, for a total of ten (10) cases to comprise the trial pool and proceed to expert discovery. *Id.* Ultimately, there was global settlement of the matters before the second discovery pool proceeded to trial. *See* Joint Notice of Proposed Settlement Program, *In re: Abilify*, Case No. 3:16-md-02734 (N.D. Fla. Feb. 15, 2019) (Dkt. at 1125). Random selection may also be as simple as picking names out of a hat. *See* Order re: Bellwether Trial Selection at 2, *In re Prempro Prods. Liab. Litig.*, MDL No. 1507 (E.D. Ark. June 20, 2005).

Judicial Selection

Judge Fallon explains that although "[b]eing an unbiased neutral, the transferee court's selections are likely to be more focused on cases that are truly representative of the litigation," this option should be avoided as the "transferee court simply does not have the resources available, or the familiarity with each individual case, to conduct this task adequately." Fallon, at 2349. This assumes that judicial selection requires cases to be chosen on their merits. However, judicial selection can be accomplished in any manner—for example, a presiding judge may identify a range of docket numbers to act as bellwether cases, instruct parties to work up the earliest filed cases, or rely on any other variable—product at issue; injury type; or even counsel (*e.g.*, cases represented by firms on the steering committee).

Furthermore, recent litigation provides an example as to how the court can guide bellwether selection while making the process less burdensome on the court. Take, for example, *In re: Taxotere (Docetaxel) Products Liability Litigation*, where the parties submitted a list of ten (10) cases to the court, where the court had original jurisdiction and venue. *See* Case Management Order No. 3, *In re: Taxotere (Docetaxel) Prod. Liab. Litig.,* Case No. 2:16-md-02740 (E.D. La. July 21, 2017) (Dkt. at 669). These ten (10) cases then proceeded to the first phase of discovery. *Id.* The parties then "nominate[d] to the Court and rank[ed] in order of preference the four (4) cases that [would] proceed to the second phase of discovery." *Id.* The Court then selected a "Primary Plaintiff" for the first trial date, and the court ranked the remaining three Plaintiffs second, third and fourth as alternates in the event that the "Primary Plaintiff" was dismissed. *Id.*

Parties may prefer judicial selection. For example, in briefing regarding proposed modifications to its trial plan, defendant Zimmer Inc. told the Illinois federal court managing the company's MDL over its knee implants that the current trial plan would waste years on lopsided bellwether cases the parties pick, pressing the court to select the cases for trial instead:

> [T]hat the next Trial Plan should avoid bellwether selection by the parties, since both sides will simply choose the best cases that they can possibly cast as representative, leaving the true middle-of-the-road cases out of the bellwether process. That is why Zimmer proposed that the Court first select the trial pool from a random selection of cases, and then also select which cases from that pool will be tried, and in what order. However, to the extent Plaintiffs have legitimate concerns about random sampling,... Zimmer would consider selection by the parties, as long as the amount of cases selected by both sides in the trial pool is equal, and the Court ultimately selects cases for trial without regard for who selected them. Zimmer believes the Court is the best arbiter of whether any new trial plan should include selection by the parties in any form.

See Reply in Support of Zimmer's Motion for Revision of Trial Plan at 12–13, *In re: Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, Case No. 1:11-cv-05468 (N.D. Ill. Aug. 31, 2015) (Dkt. at 1578). This suggests there may be instances where a party selection plan evolves into judicial selection: "[t]he judge must consider whether to override the parties' picks when it appears the parties have yielded to the pressures of advocacy by picking their best cases without regard to their representativeness." Melissa J. Whitney, Fed. Judicial Ctr. & JPML, *Bellwether Trials in MDL Proceedings, A Guide for Transferee Judges* 28 (2019).

Party Selection

Party selection can be preferable because "[t]he attorneys are in the best position to know, or ascertain, the true census of the litigation," and "[i]n addition, they have the most staff resources available." Fallon, at 2349. Party selection also has the benefit of allowing the parties to feel more invested in the selection process, which in turn makes them more likely to be willing to extrapolate results to a wider set if they chose the case that either wins or loses. However, when the case tried was chosen by the opposing side, it is easier to dismiss the case as an outlier and be hesitant to rely on it for settlement purposes.

In constructing its bellwether selection plan, the court can proactively deal with potential issues. Even when relying on party selection, the court still has the power to direct the selection process and can influence how certain injuries are represented. In the *Invokana (Canagliflozin) Products Liability Litigation*, for Group A cases, each party identified three (3) plaintiffs who ingested Invokana and subsequently developed ketoacidosis and three (3) plaintiffs who ingested Invokana and subsequently developed kidney injury to undergo "Bellwether Core Discovery." *See* Case Management Order No. 20, *Invokana (Canagliflozin) Prod. Liab. Litig.,* Case No. 3:16-md-02750 (D.N.J. July 27, 2017) (Dkt. at 218). Thereafter, a designee for the Plaintiff Steering Committee and a designated counsel for Defendants exchanged their lists. *Id.* at p. 2. The court noted that "the parties [were] strongly encouraged to select cases that they have a good faith belief are representative cases that should be robustly discovered and then taken to trial. *Id.* Following discovery, the court directed the parties to submit proposals narrowing their selections to four (4) cases, two from each injury category, to recommend for further discovery and bellwether trials. *Id.* at p. 5. The court then selected three (3) bellwether cases to serve as the first bellwether trials. *Id.* Notably, in order for the court to alleviate any *Lexecon* Waiver issues, it directed the parties to "waive applicable venue and *forum non conveniens* challenges and stipulate that the trial of any of the final... bellwether cases... [could] be conducted in the District of New Jersey without remanding any case to the transferor forum under *Lexecon v. Milberg Weiss...*" *Id.* at p. 7.

Picking the First Bellwether Trial

After picking a representative pool of bellwether cases, completing case-specific discovery, and narrowing down the pool, it is now time to pick the case that will lead the flock. According to Bellwether Trials in MDL Proceedings: A Guide for Transferee Judges,

> If possible, require counsel to agree on all bellwether cases. If the attorneys fail to agree, you may permit the plaintiffs and defendants to each choose some of the cases to try. This could skew the information that is produced, but by permitting each side a certain number of vetoes, you can minimize the chances of an unrepresentative case serving as a bellwether trial.

Citing to Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr. & JPML, *Managing Multidistrict Litigation in Products Liability Cases: A Pocket Guide for Transferee Judges* 45–46 (2011). In the *Atrium Medical Corp. C-Qur Mesh Products Liability Litigation*, the court directed the parties to select eight (8) cases, four (4) cases from each side, from the Initial Discovery Pool to proceed to expert discovery. *See* Case Management Order 3H, *Atrium Medical Corp. C-Qur Mesh Prod. Liab. Litig.,* Case No. 1:16-md-02753 (D.N.H. May 29, 2018) (Dkt. at 638). After the parties

produced expert disclosures and reports, each side was to submit a "memorandum in support of their proposed manner of trial, order of selection of plaintiffs for trial, and timing of trial(s). *Id.* at p. 4. The court noted that it would then determine same and such list would be referred to as the "Trial Cases." The *Atrium C-Qur Mesh* court stressed the importance of representativeness of the trial pick: "[t]he parties are encouraged in making selections for Discovery Pool and Trial Pool cases to select cases that will be representative of all filed cases in order that the process of selection and trial will be a helpful process for evaluation of the entire docket of cases for trial and resolution of the entire docket of cases." *Id.* at p. 5. Ultimately, the parties narrowed down the Trial Cases to two (2). *See* Order Regarding Selection of Plaintiffs for Trial and Miscellaneous Pre-Trial Matters, (Dkt. at 1169). The parties were encouraged to reach an agreement on the first case to be tried; however, if an agreement was not reached, the Court would select from the two cases selected by the parties. *Id.*

Identifying the Appropriate Selection Method

Given the importance that both parties can adequately prepare the case for trial in a timely, efficient manner, the parties should develop a case management order that addresses the trial selection process. Ultimately, as noted by Judge Fallon, "the sheer number and type of feasible trial-selection processes are limited only by the ingenuity of each transferee court and the coordinating attorneys." Fallon, at 2343. The process, then, is limited only by the creativity of all parties involved. Collaboration amongst counsel and the court is key. In designing the trial selection process, the parties will need to consider the composition of the MDL, key variables to be represented, the size of the desired pool, and each party's preferred method of selection, taking into consideration common issues such as how to handle strikes, voluntary dismissals, and replenishing the pool of plaintiffs. Regardless of what method is selected—random; judicial selection; party selection; or a hybrid model—thoughtful and cooperative engagement will be most likely to get the parties to informative, representative bellwether cases that are ready for trial.

Shana E. Russo, **Jennifer A. Eppensteiner**, **Kathy I. Oviedo** *are members of Reed Smith LLP's Life Sciences Health Industry Group, resident in the Princeton, New Jersey office. Ms. Russo, Ms. Eppensteiner, and Ms. Oviedo all focus their practices on defending pharmaceutical and medical device litigation in state and federal courts.*

Ms. Russo is a Partner and has extensive experience with all stages of pre-trial and trial workup including management of federal multidistrict litigation and state coordinated proceedings. She has been involved with various MDLs from their inception and has participated in all stages of the litigation from designing bellwether selection plans through trial.

Ms. Eppensteiner and Ms. Oviedo are Associates with experience in single plaintiff matters, as well as complex coordinated cases and federal multidistrict litigation. Ms. Eppensteiner has been involved in MDL case management and associated discovery waves. Ms. Eppensteiner currently serves as the assistant newsletter editor for the DRI Drug and Medical Device Committee as well as Young Lawyer liaison to the Drug and Medical Device Steering Committee. Ms. Oviedo is an active member of DRI. Prior to joining Reed Smith, Ms. Oviedo served as a Prosecutor for several years, where she tried numerous bench and jury trials and regularly argued motions before the court.

Remote Depositions: From Rare to Routine

By Jenna C. Newmark and Jacqueline D. Harrington


For pharmaceutical and medical device defense lawyers, criss-crossing the country and travelling the world for depositions has been a defining feature of the job. Over the years, we have found ourselves in Surrey, England for a plaintiff's deposition, Marfa, Texas to depose a treater, and midtown Manhattan to question an expert. Back in March, when the world came to a halt, we thought the COVID-19 pandemic would be over in two weeks, so we made best efforts to postpone depositions until we could travel and safely meet face-to-face again. Yet, seven months later, the pandemic endures, meeting face-to-face may be a questionable endeavor, and remote depositions have gone from rare to routine.

Although conditions in some areas have improved and we know more about how the virus spreads and proper precautions to take, many obstacles still complicate in-person depositions. Some states have mandatory quarantine requirements for people traveling from others, and Americans are unable to visit much of Europe. Lockdown orders make finding a deposition location difficult—some firms remain closed or are operating at limited capacity, and conference rooms at hotels are hard to come by when hospitality services are not operating. Air and even train travel makes many of us uneasy. Witnesses who have health conditions that make them more vulnerable to a severe outcome if infected with COVID-19 cannot risk being in a room with others. And varying attitudes towards precautions (such as mask-wearing) and the overall risk of the virus can lead to awkward conversations and even disputes that further complicate planning.

Courts have long permitted remote depositions, but they certainly have not been the norm. So, at the beginning of the pandemic, some courts and parties began to shift litigation deadlines to allow for in-person depositions once restrictions were lifted. However, other courts directed parties to move forward with remote proceedings, including depositions. For example, at the start of the pandemic, in the New York City Asbestos Litigation court, the judge directed that "[u]ntil further notice, plaintiff's counsel shall make appropriate arrangements for all counsel to appear via videoconferencing." Email from NYCAL Administrator re: NYCAL: Plaintiffs' Depositions. (Mar. 16, 2020) (on file with author).

As it turns out, remote depositions do have some perks: more flexibility, especially for those homeschooling children or caring for loved ones; lower costs to clients (crucial during this economic downturn); room at the "table" for attorneys representing many co-defendants in a big case; and comfort for sick or medically vulnerable witnesses who can appear from home. Given these benefits, it seems that remote depositions will become much more common after the COVID-19 pandemic (hopefully) becomes a distant memory.

We have taken, defended, and attended over a dozen remote depositions over the last several months and, based on that experience, offer the five tips below.

Five Tips for Remote Depositions

Tip 1. Negotiate a protocol with opposing counsel.

Given all of the potential logistical pitfalls, it is essential to establish a protocol with opposing counsel to avoid deposition-day surprises and unnecessary disputes.

Where the witness will appear. For a video deposition, as always, the parties should anticipate that any video testimony will be played back at trial before a jury. Because many of us currently are homebound, the witness likely will appear from his or her home. The parties should agree that the witness will appear in a private room with a neutral background to the extent possible. It is important that nothing in the background might unfairly sway a jury or otherwise distract from the witness's testimony. This means, for example, an expert should not appear in front of books or posters intended to induce prejudice in the minds of the jury, and a plaintiff should not appear in front of family photos intended to provoke sympathy.

Who will be physically present with the witness. It usually is ideal for a witness and counsel to be in one room. But particularly for a plaintiff who may be in extremis or other witnesses who otherwise may be medically vulnerable, the witness may feel more comfortable remaining isolated. If this is not the case and the witness and attorneys feel comfortable, they may decide to appear together. While a

videographer sometimes has been present with a witness, some court reporting services are able to record testimony remotely without being physically present. Whichever the parties choose, this should be discussed ahead of time.

What timing works for everyone. One of the benefits of remote depositions is that no travel is required. In large pharmaceutical and medical device cases, multiple attorneys may be appearing on behalf of numerous parties from all over the country. Given that everyone involved will now be attending from different locations, the deposition may need to accommodate different time zones. Where there may be vast time differences (for example, a witness located in Europe and attorneys located in the United States), the deposition may need to take place over multiple days. Similarly, the parties should anticipate the possibility that there could be more time off the record due to technological delays. For a treating physician or a medical expert witness, this also means taking into account their schedules and sometimes creatively finding extra hours in the day when they can sit for a deposition.

How exhibits will be handled. This is one of the biggest logistical challenges. In "before" times, we would make multiple copies to hand out across the table. Now, there are a few different options (discussed further below) for showing exhibits. Any pre-negotiated deposition protocol must address how exhibits will work. In general terms, a procedure that most closely mirrors the handling of documents during a live deposition seems optimal to us, especially for document-intensive depositions.

How the witness will be sworn in. In most situations, the parties have agreed to have the witness sworn in by the videographer over video as if physically present, but this should be included in a protocol to avoid unnecessary disputes.

Tip 2. Be (really, really) prepared!

If you're reading this, you've already heard hundreds of times that preparation is key to a successful deposition. But preparation looks a little different than usual for remote depositions, particularly in a pandemic.

First, it is crucial to test out the platform and practice using its different functions, including showing exhibits on the screen, in advance. Different court reporter services have been using different platforms, each of which works differently. Being familiar with which particular platform you will be using ahead of time reduces the likelihood of technological delays and deposition day frustration. Luckily, the court reporting services have helpfully made personnel available to assist. Know their names and take their numbers!

Second, pick a quiet place with good wi-fi. Video streaming does not work on a weak connection, so if you have poor internet at your vacation house in the woods, it is a good idea to find another location for your deposition. Or, ask your firm for a mi-fi if needed. Similarly, make sure your device works and is fully charged. If possible, have a backup device that can access the deposition platform in the event your primary device fails. And, make sure your location is quiet and free from distractions. Remote depositions allow us to depose from anywhere—a beach, a bedroom, a backyard, or even an office. This means, however, that there are endless possibilities for background noise not typically present in a conference room. For example, if you're outside or near an open window, anticipate that birds may interrupt or make it difficult to hear.

Third, determine in advance how you will communicate with counsel for co-defendants. In large pharmaceutical and medical device cases with multiple co-defendants, it often is helpful, and even critical, to strategize with counsel for co-defendants in breakout rooms throughout a deposition. Unfortunately, in a remote setting, this ability to caucus is limited. Thus, ahead of time, defense counsel should establish a method for communicating with each other during the deposition. Whichever method you choose, establish and agree upon this in advance.

Tip 3. Know what you're doing with exhibits.

Without adequate preparation, remote deposition exhibit technology alone can undercut your questioning or weaken your witness's ability to participate fully in a remote deposition. We have seen four different ways to show exhibits: (1) show the exhibit on a platform using screenshare technology (only one person can control the exhibit), (2) show the exhibit on a platform like Egnyte, where the witness and other attorneys obtain a copy of the exhibit that they can manipulate themselves, (3) send all exhibits by email, or (4) send physical copies of the exhibits in advance of the deposition.

The mechanism you prefer for exhibits will depend on your comfort level with the technology, the type of witness, and how document-intensive the deposition will be. For example, option 1 might work fine in a deposition where the witness is not particularly tech savvy and will only be shown a limited set of shorter documents. On the other hand, for a corporate representative deposition, where the witness could be shown larger documents spanning decades, physical copies will make the deposition far more

efficient. For plaintiff depositions involving large sets of medical records, it may make sense to have a central set of records for all participants (sent via email, loaded to a secure website, or even sent to the witness in hard copy) and then the questioning attorney can show specific sections or pages on the deposition platform. Similarly, for experts, it may make sense to agree in advance on a set of materials that all experts will have on hand at the deposition (*e.g.*, expert reports, CVs, publications, etc.).

If you are using anything other than physical copies sent to the witness in advance, the key is practice, practice, practice. Set up a demo with the court reporting service to try out how the technology works if you are taking the deposition. Consider whether the technology is really going to hamper you, and if so, you may want to have another attorney or a paralegal or even someone at the court reporter's firm handle showing the exhibits for you. For depositions you are defending, you should set up prep sessions for your witnesses so that they can understand the platform in advance of their depositions. Figure out if one screen or two screens will work better for you (and your witness, if applicable).

Tip 4. Guard confidentiality.

For remote depositions—where attorneys, witnesses, court reporters and videographers are spread out across the country (often in their own homes)—guarding confidentiality is critical. Particularly in the case of corporate representatives or other corporate employees, your clients likely have significant confidentiality interests at stake, including potential trade secrets and other highly sensitive business information. Be sure you think about how you will maintain confidentiality in advance of the deposition. Consider, for example, how you are transmitting documents and make sure the platform is secure. Do not send physical copies of any exhibits that are subject to court restrictions or confidentiality unless you know the witness will be able to abide by the terms that govern their treatment (*e.g.*, adhering to confidentiality by returning them to you).

During an in-person deposition, you can see the whole room. But one drawback of remote depositions is that only the witness is usually visible on the camera. You can request an additional camera view of what the witness is viewing in your protocol, but that may not always be feasible. Whether you can see the room or not, be sure to question the witness under oath to ensure that no one else is in the room during the deposition. It is also wise to request that all attorneys on the phone identify themselves (as is the case for in-person depositions) and all attorneys on the video platform have their full name displayed.

With proper advance planning, remote depositions can provide a secure way to discuss even highly confidential information.

Tip 5. Don't let the technology undermine the deposition.

If the technology is not working, stop the deposition. Sometimes you have a deposition where the technology works flawlessly, all the exhibits load quickly, nobody loses internet, and everybody can hear throughout the deposition. Sometimes unicorns also show up for the deposition.

Remote depositions are definitely prone to more logistical difficulties than in-person depositions and you must be prepared going into the deposition for any issues that might arise. But if your ability to question a witness is being undermined or if a witness you are defending is not getting a fair shake because of the technology, stop the deposition. As just one example, the questioner at a recent deposition was putting up a critical impeachment document and the videographer's equipment crashed after the document was up on the screen. The document was on the screen for a few minutes while the videographer got back online but by the time the deposition resumed, the witness had had several minutes to consider her answers and the document was nowhere near as effective. When major issues arise during the deposition, it is best to break and resume at a later time or date when technology issues can (hopefully) be resolved.

If you are in a jurisdiction where communications at breaks are prohibited and not privileged, consider asking the witness about these just as you would at an in-person deposition. Similarly, ask if the witness has done any research into any substantive issues on a computer? And if you are defending a deposition, consider how you will communicate with the witness on any requests for legal advice that the witness may have throughout the day, while still being mindful of privilege issues.

Conclusion

Our take is that remote depositions in general terms are not so bad and can be effective. Of course, for certain witnesses, such as a critical witness being deposed with many documents, in-person depositions certainly are preferable. But for less significant witnesses located far away, remote depositions can be a far more efficient, convenient, and less expensive way to handle depositions. This can be par-

ticularly true in pharmaceutical and medical device cases, where witnesses, experts, treaters and their attorneys are spread throughout the country (or even abroad), and many, many depositions are often held on a compressed schedule. At the end of the day, do we think attorneys will continue to conduct as many depositions remotely even once this pandemic ends? We don't. But we do think that attorneys would be wise to start incorporating remote depositions into confidentiality agreements and deposition protocols moving forward, and familiarizing themselves with the types of video platforms available. While we don't think remote depositions will be universal, we do think they are here to stay.

Jenna C. Newmark *is an associate at Dechert LLP in New York. She represents manufacturers of consumer products, pharmaceuticals, and medical devices in product liability and mass tort cases nationwide.*

Jacqueline D. Harrington *is an associate at Dechert LLP in New York. She practices in the area of complex litigation, with a focus on product liability and mass torts.*

Revisiting the Gotcha Question One More Time

By Matthew Keenan

Presidential politics gave us the gotcha question, but these days it is embraced in many aspects of our culture. Take HR, for instance. With the economy rebounding, those among us looking for new work are prepping for these kinds of questions:

- What is an example where you did something you were ashamed of?
- What is an instance where you failed?
- How do you explain the gaps in your resume?
- How would your worst enemy describe you?
- What is your biggest failure?

It would be a modest understatement to say that this tactic has entered the world of company witness depositions, particularly in the universe of litigation impacting drug and medical device manufacturers.

This article is designed to offer a basic set of tools to make sure they are ready.

Big Picture: The Essence of the Hazard

The gotcha question at its core is ignorance of things that others might expect you to know. At a basic level, you need to make sure your witnesses have an understanding of liability issues that the jury—empaneled perhaps years later and miles away—would expect them to know. These include:

- The core issues in the lawsuit, including plaintiff's name and injuries
- Awareness of potential product hazards and safety measures
- Why the product was recalled
- Statements by regulatory agencies that cannot be challenged
- Themes advanced in the trial
- Public statements from the company that bear on PR
- Employee Code of Conduct and ethical obligations that may apply to the profession

Every case will be different, and ideally by the time your witness is deposed, the key issues are crystalized. One tip I've learned along the way to help identify how questions are framed is to use word indexes for what I call "hot words"—terms that are built into their themes and will most certainly raise their head again.

Knowledgeable, but Tone Deaf

Not long ago being tone deaf was the domain of the Kardashians. Not anymore.

Social media has made everyone an expert—and a critic—in everything. Every counsel should be on guard to not unwittingly allow your witnesses to give the plaintiff's bar more ammunition. They have plenty already. Witnesses must navigate the delicate balancing act of defending, for instance, a product that is safe only when used properly.

Beth Devlin, a jury consultant from Edge Litigation Consulting, LLC, underscored the delicate balance witnesses need to strike: "The witness (and the trial team, for that matter) need to not be afraid to show empathy toward the plaintiffs. For that reason, you should encourage your witness to show compassion toward the plaintiff. I think what happens all too often is that the well-intentioned trial team, in the full throes of 'advocacy' mode, tend to dehumanize the plaintiff and forget that something unfortunate happened to that individual and/or they are suffering—even if it wasn't the defendant's fault."

More than anything else, witnesses need a keen understanding of the tried-and-true themes of profits over safety, profits over people, claims of lack of testing, cutting corners or rush to market. These days it may seem difficult to believe anyone would need to be educated on these concepts, yet, preventive measures should be on your checklist. At its core, the deposition preparation process requires the witness to understand and appreciate their role in the entire defense of the case. This includes visual cues of how depositions are played and used to both help and hurt the defense.

"When the jurors first hear about the case, that is where their mindset is. We consistently see that when a witness or a lawyer expresses genuine compassion for the plaintiff, jurors do not mistake it as an 'admission of guilt' as lawyers often fear. Rather, it serves to the witness' advantage in that it humanizes them and softens the stereotypical 'corporate' appearance, and can give the witness an instant credibility. So expressing genuine empathy is one way a

witness can be perceived as effective and credible," Beth adds.

In a recent MDL, I defended a witness for six days of depositions. When it was over, his observations were useful: "I didn't appreciate how attorneys will try to find isolated moments and exploit them. Sure, you know the case and the core facts, but that isn't where they will focus," he said. "You can have the science on your side, the facts on your side, but that is no safe harbor. They will try to create a picture of what you didn't mean or intend."

Someday long ago, the totality of deposition preparation consisted of telling the witness four words: "just tell the truth." If you long for those days, you have a lot of company. Today, the hazards of witness preparation are much more complicated.

There are times, of course, where the gotcha game is folly. Consider that in 1999, then-Texas governor and Republican presidential candidate George W. Bush had this question posed: name the leaders of four countries where the USA was engaged—Chechnya, Taiwan, India, and Pakistan. Bush was able to name only the leader of Taiwan.

In 1999, no one cared about the leaders of Iraq or Al Qaeda.

Matthew Keenan *is a partner at Shook, Hardy & Bacon in Kansas City, Missouri where he has practiced for 35 years. His primary focus is the preparation and defense of corporate employees in MDL proceedings, with a focus on sales and marketing witnesses. Matt is a new member of DRI, and serves on the board of Legal Services Corporation, the country's largest funder of civil legal aid for low-income Americans.*

Young Lawyers Special Feature

Invaluable: Client Service from an In-House Perspective

By Anne A. Gruner and Jennifer A. Eppensteiner


A cornerstone of the Drug and Medical Device Seminar for Young Lawyers, among the sessions for 2020's *virtual* YL Blockbuster will be a panel discussion featuring in-house counsel from Eli Lilly and Company, Sanofi-Aventis US, Smith & Nephew Inc., and UCB Inc. Join us on Thursday, November 5, 2020, for Invaluable: Client Service from an In-House Perspective, and more. This is a can't miss panel, as our in-house panelists share their unique insights as to how associates can make themselves stand out as all-stars and offer advice regarding common pitfalls to avoid.

For example, our panelists will cover the below and more:

What advice can you offer on how associates can get to know the business of a client?

Do your research on the company in advance, and don't bill the client. Don't be afraid to ask questions. Humility is better than arrogance. *Adam Bassing, Head of Global Litigation, Patient Safety and U.S. Talent, Global Legal Affairs, UCB, Inc., Smyrna, GA.*

What are your pet peeves when it comes to outside counsel?

Receiving written work product that is not in final form or very close to it, and not being informed timely about case activity. *Munjot Sahu, Counsel – Litigation and Legal Compliance, Eli Lilly and Company, Indianapolis, IN.*

Share an experience where you were impressed by outside counsel being proactive.

One of the law firms that is handling a major litigation for my company learned of a new case that had been filed against us. They reached out to me and offered to handle the new case within their fixed fee for the major litigation. Efforts like this are not uncommon from this firm and are why I often think of them whenever new matters come in the door. *Jonathan Amar, Corporate Counsel, North America Litigation & Investigations, Sanofi US, Bridgewater, NJ.*

Anne Gruner *and* **Jenn Eppensteiner** *currently serve as Young Lawyer liaisons to the Drug and Medical Device Steering Committee.*